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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,279	09/11/2006	Jurgen Schulein	2619.001US1	6389

21186 7590 03/17/2010

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EXAMINER	
PREGLER, SHARON	
ART UNIT	**PAPER NUMBER**
1797	

NOTIFICATION DATE	DELIVERY MODE
03/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/563,279	SCHULEIN ET AL.	
	Examiner	Art Unit	
	Sharon Pregler	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-88* is/are pending in the application.

4a) Of the above claim(s) *79-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-78* is/are rejected.

7)☒ Claim(s) *69 and 71* is/are objected to.

8)☒ Claim(s) *60-88* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. On February 9, 2010, **Marvin Beekman** called to respond to the telephone call of January 26, 2010 requesting election, which was subsequently mailed on February 17, 2010. Mr. Beekman elected Group I, claims 60 – 78, without traverse. The written restriction mailed February 17, 2010 is withdrawn and replaced with this Office action.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

4. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

5. **The abstract of the disclosure is objected** to because legal phraseology often used in patent claims, such as "means" and "said," should be avoided.

6. "Cylindcr" is misspelled on line 2 in the abstract.

7. Correction is required. See MPEP § 608.01(b). Applicant is reminded of the proper language and format for an abstract of the disclosure.

Claim Objections

8. **Claims 69 & 71 objected** to because of the following informalities: "engagable" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claim 65, 73-76 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. **Regarding claim 65,** it is unclear what is specifically defined by temperature unit, a sieve, a filter, a membrane, an affinity matrix, a pre-stored substance, or a magnet in the microfluidic apparatus.

11. **Claim 73-76** recites the limitation "detent." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

> to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. ***Claims 60-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haxo Jr. et al. US Patent 6,143,252 (hereinafter "Haxo") in view of Hobbs et al. US Pre-Grant Publication 2002/187557 (hereinafter "Hobbs").***

13. **Regarding claims 60, 61 & 78, Haxo teaches** an apparatus *(See figure 4)* (automated regarding claim 78, *see column 2 line 17)* with at least two disposable containers *(figure 1 & 4 column 6 lines 25-30)*, each container comprising a cylinder *(cylinders 104, 106, 108, 110; figure 4)* and a plunger *(plunger 114 disposed in each cylinder). (See Haxo figures 1-4, column 6 lines 25-30, and column 9 lines 40-50).*

14. Haxo does not teach the containers fluidly connectable to a microfluidic device with channels. Instead, the apparatus is connected to a multiwell plate *(164, figure 8)*.

15. Haxo also does not explicitly teach that the containers are disposable. However it is of within ordinary skill in the art to make the containers disposable for the benefit of avoiding cross-contamination due to reuse.

16. However in the analogous art of injecting fluids in micro-devices, Hobbs teaches a microfluidic device *(device 120, figure 5A & 6),* the microfluidic device comprising at least one channel (plurality of interconnected channels regarding claim 61) *(columns 138-140 are fluidly connected to injection channel 131A, figure 6, [0076])* containers *(syringes 150 & 151, figure 6)*

fluidly connectable to the microfluidic device *(device 120)* for the benefit of pumping fluid in a microfluidic device. *(See Hobbs figures 5A-6, [0076]).*

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the microfluidic device of Hobbs with the cylinder pumps of Haxo for the benefit of pumping fluid in a microfluidic device.

18. **Regarding claims 62 Haxo teaches** apparatus of claim 60. It is well known in the art that microfluidic device may have at least one chamber selected from the group consisting of a microfluidic mixing chamber, a microfluidic reaction chamber, a microfluidic detection chamber, a bubble trap chamber, and any combination thereof.

19. **Regarding claims 63 & 64,** it is well known in the art that microfluidic channels are less than the diameters of 1.5mm to 2mm. Furthermore, Hobbs discloses the internal diameters of the capillary columns, or channels, in the microfluidic chips of between 3-200 microns. *(See Hobbs [0005])*.

20. **Regarding claims 65, Haxo teaches** the apparatus of claim 60, but does not teach the microfluidic device.

21. Hobbs teaches the microfluidic device includes at least one component selected from the group consisting of a sensor *(sensors and probes [0078])*, an *(electrode electrodes are placed in the channels [0079])*, *(Detectors 167 may be disposed within the microfluidic device, [0015]) & [0077]).* "Channels" and "chambers" may be filled or may contain internal structures comprising, for example, valves, filters, stationary phase media, and similar or equivalent components and materials. Therefore it is obvious to include other well known mechanical manipulators (a sieve, a filter, a membrane, an affinity matrix, a pre-stored substance, a magnet) and separators used in the art or other detection means (temperature unit) for the benefit of controlling or detecting fluids.

22. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to include separation or detection means above for the benefit of controlling or detecting fluids.

23. **Regarding claims 66 & 67, Haxo teaches** the apparatus of claim 60 associated with a multiwell plate with a closure member *(apparatus 162 in figure 8, column 11 lines 15-30 & 53-55. Closure member or nozzles 174*

interact with the plate 164 to deliver chemical reagents). Haxo does not teach the apparatus in conjunction with a microfluidic device.

24. Hobbs teaches the microfluidic device further comprises an inlet opening *(inlet ports 129A-B)* operatively associated with the channel *(to columns 138-140 through channel 131 & 131A)* to sealably deliver fluid to the device further comprising an outlet opening *([0051])* operatively connected to the channel and a second closure member *(figure 11 fluid connections 192)* (regarding claim 67). *(See figures 8, 10 & 11 column 11 lines 15-30 & 53-55).*

25. It would be obvious to one of ordinary skill in the art at the time of invention to replace the multiwell plate with a microfluidic device and incorporate closure members at the inlet to sealably deliver fluid to the device.

26. **Regarding claims 68, Haxo teaches** the apparatus of claim 67, wherein at least one of the first and second closure members comprises a valve *(three way valve 166)*. *(See figures 8 & 10).*

27. **Regarding claims 69, Haxo teaches** the apparatus of claim 60, further comprising first and second connectors, wherein the first connectors *(*are operatively connected to each disposable container and wherein the second connectors are operatively connected to the microfluidic device (here multiwell plate), wherein the first connector is operatively engageable with the second connector. *(See figures 8 & 10).*

28. **Regarding claims 70-76 Haxo teaches** the apparatus of claim 69, (Hobbs teaches the use of microfluidic device instead of Haxo's microwell plate, see above) includes a recess corresponding to the external diameter of the container *(lower end 28 & tip holder 44)*, the recess providing guidance of the first connector into a position of engagement with the second connector *(engages with pipette in figures 1-3)* (regarding claim 70), wherein the microfluidic device is engageable in a fixed position relative to the second connector (regarding claim 71), wherein the disposable container is maintained in the fixed position by a frictional engagement of the disposable container in a microfluidic device recess (regarding claim 72), wherein the microfluidic device recess comprises a first detent and a second locking detent along the circumference of the recess, each of the detents spaced apart along

the length of the recess (regarding claim 73) the apparatus of claim 73, wherein the containers each include a closure and wherein distance between the first detent and the second detent allows for insertion of the disposable container into the recess and engagement of the first detent without opening of the disposable container closure, wherein the second detent engages the disposable container in liquid-tight engagement wherein upon engagement of the second detent with the disposable container, the disposable container closure is opened. *(See figure 8-9A, where raised walls of the microwell plate matingly engages the nozzles for a closure).*

29. The microfluidic device in Hobbs figures 9A - 9C provides an expanded view of a portion of the device 200, focusing on the sample injection channels 235A-235H and associated separation channels 245A-245H. Each sample injection channel 235A-235H has an associated enlarged region 234 that is aligned with a sample inlet port 228A-228H defined in the first layer 201. FIGS. 9A-9B show the frit 240 placed between the sample vias 236A-236H, 244A-244H upstream of the point where samples are injected onto the separation channels 245A-245H to be filled with stationary phase column material. *(See Hobbs figure 8-9C [0088]).*

30. It would have been obvious to one of ordinary skill in the art to make the microfluidic device engageable, or frits, with the containers for a secure fit during dispensing.

31. **Regarding claims 77, Haxo teaches** the apparatus of claim 60, Hobbs teaches the use of the microfluidic chip *(see above)* and pre-stored with micro-particles: including Liquid-Liquid, Liquid-Solid (Adsorption), Size Exclusion, Normal Phase, Reverse Phase, Ion Exchange, and Affinity. *([0005]).*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Monday through Friday 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797